



May 12, 2004

Division of Dockets Management (HFA -305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Via e-mail: <http://www.fda.gov/dockets/ecomments>

RE: Comments on Interim Final Rule on Registration of Facilities, Docket No. 2002N-0276

Dear Sirs/Madams;

FedEx Trade Networks Transport & Brokerage, Inc., (FTN) strongly supports the efforts of the Food and Drug Administration (FDA) to protect the U.S. food supply. We respectfully offer the following comments on the interim final rules as published in the Federal Register of April 14, 2004, Docket No. 2002N-0276.

- ?? **Foreign facility designation of U.S. agent:** Our experience with the Bioterrorism Act (BTA) agent designation process is less than favorable. A foreign party that is required to register can merely complete the BTA registration on-line and successfully file it without ever having initiated any contact with the designated U.S. agent. We have received sporadic "post facto" notification that many of our individual employees have been designated without their knowledge or consent.
- ?? **Notification to U.S. agent:** FDA currently notifies the designated U.S. agent by e-mail, but only if the registration application included an e-mail address for the designated U.S. agent. This practice is less than acceptable for the reason cited above. FDA should have a clearly defined notification process, either by e-mail or, failing that, notification by letter.
- ?? **Listing of designations:** A company that acts as U.S. agent should be able to obtain a listing from FDA of all parties that have designated that company as U.S. agent.
- ?? **Validation of registration number:** Submitters and transmitters need the ability to verify or authenticate the registration number in order to provide adequate prior notice. FDA previously has stated that registration numbers are confidential and not subject to Freedom of Information Act requests. A process to provide an encrypted number for use in these situations should be established similar to the Bureau of Customs and Border Protection encrypted number procedure for Ultimate Consignee IRS numbers.
- ?? **Process to rescind U.S. agent status:** The designation of U.S. agent portion of the registration process needs to add functionality allowing the designator to rescind that status. Examples of the need for this functionality are improper designation as cited above, or a change in business relationships between the foreign party and the U.S. agent.
- ?? **One Time U.S. Agent:** The casual importer of food products needs a less formal process and the ability to designate a one time U.S. agent (if a "de minimis" value exemption to prior notice filing is not established).

FTN strongly encourages FDA to adopt the above recommendations for improvements in the facility registration process. Thank you for your considerations.

Yours truly,

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